



TEXAS
Health and Human
Services

**Texas Department of State
Health Services**

Video-Based Directly Observed Therapy



Required and Recommended Activities

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A. Purpose

This document describes the position of Texas Department of State Health Services (DSHS) regarding the implementation of video-based directly observed therapy (VDOT), a supportive intervention for tuberculosis (TB) medication administration and assessment. It outlines required and recommended activities for TB programs implementing VDOT using state-purchased medications for the treatment of TB disease or infection. This document aims to promote consistent application of VDOT practices statewide and serves as a framework for implementing VDOT. It also aligns with the Centers for Disease Control and Prevention's (CDC) TB Guidelines for Infection Control.²

The DSHS does not recommend any one VDOT platform; however, there are basic requirements all TB programs should follow as outlined in this document.

Although this guide provides a basic framework for implementing VDOT, TB case management practices must continue to align with DSHS Standing Delegation Orders (SDOs), Standing Medical Orders (SMOs) and Texas Tuberculosis Work Plan found at DSHS Tuberculosis and Hansen's Disease Branch website, www.texas.tb.org.¹

B. Background

Directly observed therapy for the provision of TB medications to clients is the standard of care in Texas. The CDC, as well as the World Health Organization, recommend DOT as the only documented evidence-based intervention that ensures clients are cured from tuberculosis using a supervised medication adherence regimen.³ Video-based DOT presents an opportunity to use technology to achieve direct observation, allowing healthcare workers to allot more time for in-person DOT with those clients who need it most. Implementing a VDOT program requires adherence to all current, approved SDOs and SMOs, that technology is chosen based on federal and state privacy and security laws, and that chosen candidates are ideal for the intervention.

C. Definitions

Asynchronous video - video that is recorded and stored, before being delivered for review. This is different than live video.

Business Associate - a person or entity that performs certain functions or activities that involve the use or disclosure of protected health information on behalf of, or provides services to, a covered entity. Third party vendors handling PHI are considered Business Associates.⁴

Directly observed therapy (DOT) - a process by which a trained health care worker or other designated individual (excluding a family member) provides the prescribed medications to a client and watches while that client swallows every dose.

Protected Health Information (PHI) - individually identifiable health information that is: 1) transmitted by electronic media; 2) maintained in electronic media; or 3) transmitted or maintained in any other form or medium.⁴

User - a healthcare worker employed or contracted by a health care entity with authorization to access and review client videos submitted by the client for video DOT.

Video-based directly observed therapy (VDOT) - the use of electronic technologies such as a videophone or other video/computer equipment to remotely monitor/observe TB clients ingesting their medication, either in real-time or recorded. This type of DOT is sometimes referred to as virtually observed therapy (VOT), mobile DOT (mDOT), remote DOT, electronic DOT (eDOT), and video-enhanced therapy (VET). This method is promising as a flexible and less invasive option to help ensure TB clients complete their treatment successfully.

Wi-Fi - a trademarked term identifying the technology that allows computers, smartphones, or other devices to connect to the Internet or communicate with one another wirelessly within a particular area.

D. Basic Requirements to Implement Video-Based Directly Observed Therapy

Data and Security Requirements

TB programs must maintain security standards for the protection of client information and assurance of privacy. In initiating VDOT, it is important to implement policies that ensure both privacy and security for all parties involved. Some products that allow for VDOT capabilities may not be compliant with the Health Insurance Portability and Accountability Act (HIPAA), and some may use a version of text messaging as a means of communication. As general text messaging is not HIPAA-compliant, local

health departments **must** have a formal text messaging policy if the chosen VDOT software prompts text messaging alerts.

The following requirements must be met by TB programs choosing to initiate VDOT:

1. Comply with HIPAA. Protected Health Information (PHI) must be encrypted and transmitted to recipient securely, in the least amount of time possible. The third party vendor must operate under a Business Associate Contract, as outlined by HIPAA laws. Access to systems must require authenticated user logins, to access appropriate software functions.
2. Obtain written informed consent from the client that documents⁶:
 - a. Client's and health care worker's role in the use of technology.
 - b. Permission for use of technology.
 - c. Implications of technology use and potential confidentiality concerns.
 - d. Alternatives to VDOT.
 - e. Conditions for initiating and discontinuing the use of VDOT as an intervention.
 - f. Risks and benefits for the use of VDOT.
 - g. Assurance of explanation and understanding.
 - h. A notification that a geographic stamp may identify the location of a client where the video was recorded.⁷
 - i. Directions for maintenance of phone equipment, phone return, and protocol for loss of phone or equipment failure.⁷
 - j. An additional form stating the proper use of technology is recommended, if technology is issued by the health department.⁸
3. Adhere to DSHS contract requirements:
The DSHS contract agreement requires local health departments to develop and maintain a policy on VDOT prior to implementing VDOT. The policy should be written to reflect the health department's philosophy on the use of VDOT. This guidance manual reflects the minimum requirements, and can be included as part of a local TB program's VDOT policy.
4. Adhere to technology requirements
 - a. The application must be able to capture and transmit client data using cellular data or Wi-Fi, even with no connectivity. If there is no connectivity, the application must be able to store encrypted data until connectivity is established. Once connectivity is established, the application will transmit the encrypted data to the

server, and immediately delete encrypted information from the mobile device. The application must be capable of transmitting transmission errors.

- b. Use cell phone or desktop video with camera and audio capability for all users.
- c. Use secure, HIPAA-compliant application that supports VDOT capabilities.

Texas State Board of Pharmacy Rules and Regulations

Medications must be provided to clients and labeled according to Texas State Board of Pharmacy Rules and Regulations. The medication label should include a place for the health professional to write:

1. Client's name;
2. Prescribing physicians name;
3. The date medication was dispensed;
4. The name and strength of the medication;
5. Instructions for use including number of tablets to be taken and frequency;
6. Expiration of medication;
7. Name, address, and phone number of dispensing pharmacy;
8. Quantity of medication dispensed; and
9. Manufacturer of medication.

There must only be one medication per label that must be affixed by a registered pharmacist.

Requirements to Submit Medication Orders to DSHS Pharmacy

1. To gain ITEAMS access to the TB VDOT program, complete and email the New User form to the TB and Hansen's Disease Branch at Diana.Whitley@dshs.texas.gov
2. TB VDOT orders will be requested under the Bulk Order tab and will require a patient identification number. Information to include in the Special Instruction box: quantity, patient identification number, and prescription label instructions.
3. Complete **all** transactions prior to reconciling (Receiving, Doses Administered, Transfer Order, Wasted/Expired).
4. Reconciling (Provider C-33) should be done at least every 30 days.

5. Shipping and processing orders will have a one to two-day turn-around.
6. Contact the Pharmacy Branch if a drug item does not appear on the ordering formulary or on the doses-administered screen.

For customer service support, contact DSHS Pharmacy at the following:

- a. Pharmacy Branch's Main Line: 512-776-7500
- b. Helpdesk: ITEAMS.PharmacyHelpdesk@dshs.texas.gov
- c. ITEAMS Website: <http://www.dshs.texas.gov/ITEAMS/>

E. Recommendations for Using Video-Based Directly Observed Therapy

Indications for VDOT

The following describes indications for clients suitable for VDOT intervention:

1. Any client recommended for DOT for TB disease or TB infection.
2. Clients unable to travel to clinic, or reside in an isolated location who prefer the use of technology as an intervention.
3. Clients interested in utilizing technology as an incentive for the completion of treatment.
4. Clients who may otherwise feel stigmatized.
5. Clients who can better accommodate medication adherence through the use of VDOT due to demanding work and/or school schedules.⁹

A client may change from VDOT to standard DOT as needed, based on an assessment of the health care provider.

Inclusion Criteria

The following considerations should be made when choosing which clients can receive VDOT.

1. Treatment history while on DOT
 - a. acceptable medication adherence via DOT history based on provider assessment

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- b. completed initial treatment phase with known susceptibilities or stabilized on treatment for at least two weeks and non-infectious
 - c. Greater than one month of treatment remaining
 2. Age Requirements
 - a. receive written informed consent by client or guardian where appropriate
 3. Residence
 - a. stable place of residence
 - b. access to private location⁸
 4. Language
 - a. speaks language that can be accommodated^{7,10}
 5. Additional criteria
 - a. successful completion of VDOT training sessions
 - b. accurately identifies medications and demonstrates proper use of technology/application¹⁰
 - c. not on isolation
 - d. no medication adherence/contraindication concerns¹¹
 - e. motivation factor and understands course of treatment⁷
 - f. reliable internet connection or cellular connectivity¹⁰

Exclusion Criteria

The following circumstances are recommendations for clients not suitable for VDOT.

1. Substance abuse is suspected^{7,12}
2. Low adherence to DOT⁸
3. Court-ordered DOT⁸
4. Homelessness^{7,8,12}
5. Medication intolerance/adverse reactions^{8,11}
6. Slow acid fast bacilli sputum smear/culture conversion
7. Minors without an accompanying adult
8. Persons with disabilities that prevent full participation in VDOT such as hearing or vision impairment or other physical challenges.
9. Psychiatric concerns^{7,10}
10. Language that cannot be accommodated
11. Memory impairment⁷
12. Hepatic complications⁸
13. Prior history of TB disease where non-compliance to treatment is documented⁷

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14. Receiving injectable anti-TB medications⁸
 15. Current Incarceration⁸

Video Observation and Assessment

A successful video observation occurs when a health care professional watches the video and confirms they have observed the client take their medication. The medications should be verified and side effects captured either by client's voice or digital entry.

The video assessment should include verification of client's identity and an acceptance or rejection of the video. If the video is rejected, the health care professional must document reasons for rejection. Some clients may require a longer time to take their medication and will submit more than one video within a 24-hour period.

Recommendations for Clients Enrolled in VDOT

The following are recommendations for enrolling clients in VDOT.

1. Initial Enrollment
 - a. Prior to enrolling clients for VDOT, the health care provider must determine client's suitability for VDOT. Refer to the inclusion and exclusion criteria provided above. The provider or program designee then trains the client on the use of video technology, and ensures all appropriate written consents are obtained as described in Section D above.
 - b. The number of client training sessions is based on provider assessment or local program's policy.
 - c. The training session must ensure client is able to accurately identify each medication.^{7,8}
 - d. DOT packets containing multiple medications cannot be used for VDOT; therefore, labeled containers such as medication bottles must be provided to the client for VDOT purposes. Provide sufficient medication supply until the next face-to-face visit. VDOT does not take the place of face-to-face visits as required by SDO protocol.
2. Video Competency Recommendations - Client must be able to:
 - a. Show full face in view at all times.⁷
 - b. Demonstrate use of equipment effectively during training period.

Monitoring Side Effects

A client must be able to use the technology to inform the health department of any symptoms or side effects in a timely, straightforward, and intuitive manner. The selected video technology should include a menu that is customer-friendly either in plain text or images, for clients to select symptoms or side effects. If plain text is used, the client must be literate and the language of the text must be understood by the client.

Clients should be instructed not to ingest medication if they exhibit any new side effects due to the medication. If the client reports a side effect, the video technology must inform the client not take their medication, and prevent the client from recording a video. Upon submission of a symptom or side effect, the video technology must trigger SMS and/or notification to individuals at the health department and/or the client. Symptoms and side effect submissions must also be visually displayed to the health department via a web interface.⁹

The list of side effects a client should be able to report are listed below:

Headaches (chronic)	Skin rashes/itching	Jaundice (yellow skin/eyes)	Fever (+3 days)
Joint pain (chronic)	Sores on lips or inside mouth	Abdominal Pain	Convulsions
Ears Ringing/Fullness	Visual Problems	Nausea/Vomiting	Unusual bleeding
Numbness/Tingling	Dark Urine (coffee colored)	Malaise/Fatigue	Other

Form TB-206 DOT log¹⁴

Indications for Stopping VDOT

The following circumstances may dictate a need to stop VDOT, and return to the standard in-person DOT intervention:

1. Adverse reaction to TB medications^{7,10}
2. Unstable housing situation⁷
3. Unanswered/missed calls or <80% medication adherence⁷
4. Other compliance issues (missing appointments, dishonesty, inappropriate use of technology)⁷

5. Client change in inclusion/exclusion status¹⁰

Treatment may be restarted if issues are resolved, and all parties agree.¹⁰

VDOT Staff Competencies

The following list of staff competencies are recommended for individuals who currently provide DOT, and who will be engaging in VDOT. These competencies do not replace basic required competencies as provided in the SDOs.

Staff responsible for using VDOT technology must be trained by an individual qualified to effectively convey the information. All trainings must be documented and maintained. Trainings should include the following topics⁷:

1. Use of client device or personal computer and VDOT application software.
2. Troubleshooting: how to erase application and re-download on client's device.
3. How to teach client to download application on phone (if applicable).
4. Provide consent forms (medical, phone agreement form, use of app form).
5. Be prepared to contact client if VDOT was not successful due to technical/client issues.
6. Provide client education with a written guide including:
 - a. how to download application (if applicable)
 - b. what to do in an emergency if technical issues arise
 - c. plan for alternative face-to-face DOT with included stipulations
7. Document each client encounter.

Staff responsible for assessing a client's mental and physical ability to engage in VDOT, must be trained and competent to perform this assessment.

TB programs shall comply with all applicable federal and state regulations and statutes, including but not limited to, the following:

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1. Tuberculosis Code, Texas Statutes, Health and Safety Code, Chapter 13, Subchapter B;
 2. Communicable Disease Prevention and Control Act, Texas Statutes, Health and Safety Code, Chapter 81;
 3. Control of Communicable Diseases, Texas Administrative Code TAC, Title 25, Part 1, Chapter 97, Subchapter A; and
 4. Retention of Medical Records, General Provisions Article VIII "Records Retention" and by Texas Administrative Code Title 22, Part 9, Chapter 165, §165.1.

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